



IFW 1616/\$

Docket No. MCP0289

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : McNally, et al.

Serial No. : 09/924,319

Art Unit: 1616

Filed : August 8, 2001

Examiner: F. Choi

For : LAXATIVE COMPOSITION

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

January 27, 2006

(Date of Deposit)

Michele G. Mangini

(Name of applicant, assignee, or Registered Representative)

/Michele G. Mangini/
(Signature)

January 27, 2006

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Supplemental Information Disclosure Statement is supplemental to the Information Disclosure Statement mailed on 13 September 2005.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

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information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☒ Please charge Deposit Account No. 10-0750/MCP0289/MGM the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☒ Copies of foreign patent documents and non-patent literature, which were previously submitted in a parent application, are not enclosed herewith in view of the likelihood that these references are available to the Examiner.

☒ Notwithstanding the above, if any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☒ Attached are the following related patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

<u>Internal No.</u>	<u>U.S.S.N.</u>	<u>Related Foreign Publication No.</u>	<u>Publication Date</u>	<u>Filing Date</u>
MCP 0227	09/390,813	EP1086701A2	28 March 2001	7 Sept. 1999
MCP 0255	09/538,008			29 March 2000

Please charge any deficiency or credit any overpayment to
Deposit Account No. 10-0750/MCP0289/MGM. This form is
submitted in triplicate.

Respectfully submitted,

/Michele G. Mangini/
Michele G. Mangini
Reg. No. 36,806
Attorney for Applicants

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DATED: January 27, 2006



PTO/SB/08A (08-00)
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Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 6

Application Number	09/924,319
Filing Date	August 8, 2001
First Named Inventor	McNally
Group Art Unit	1616
Examiner Name	Choi, Frank
Attorney Docket Number	MCP0289

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		5,262,418		VanDaele et al.	11/16/1993	
		5,854,260		VanDaele et al.	12/29/1998	
		5,858,403		Borody et al.	01/1999	
		5,716,641		Stevens et al.	02/10/1998	
		5,834,004		Upmeyer et al.	11/10/1998	
		5,843,479		Kelm et al.	12/01/1998	
		4,195,084		Ong, J.	03/25/1980	
		5,120,533		Schmidt et al.	06/09/1992	
		5,277,902		Schmidt et al.	01/11/1994	
		5,393,745		Schmidt et al.	02/28/1995	
		5,418,220		Schmidt et al.	05/23/1998	
		5,424,064		Schmidt et al.	06/13/1995	

FOREIGN PATENT DOCUMENTS

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		Office ³ Kind Code ⁵	Number ⁴					
		WO	95/25545	A1	Schmidt et al.	09/28/1995		
		WO	98/56356	A1	Reckitt & Colman Products Limited	12/17/1998		
		EP	0 015 334	B1	J.B. Tillott Limited	09/17/1980		
		WO	96/40079	A1	Emory University	12/19/1996		
		WO	95/00973	A1	Vlsi Technology	1/05/1995		

Examiner Signature		Date Considered	
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 2 of 6

Application Number	09/924,319
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First Named Inventor	McNally
Group Art Unit	1616
Examiner Name	Choi, Frank
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		Number	Kind Code ² (if known)			
		5,525,605		Omura, S.	06/11/1996	
		5,599,577		Stevens et al.	02/04/1997	
		5,679,376		Stevens et al.	10/21/1997	
		5,834,479		Kelm et al.	12/01/1998	
		5,578,312		Parrinello	11/26/1996	
		5,569,466		Tanner et al.	10/29/1996	
		4,327,076		Puglia et al.	04/27/1982	
		5,431,914		Adekumle et al.	07/11/1995	
		3,196,827		Wurster et al.	07/27/1965	
		3,253,944		Wurster et al.	05/31/1966	

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		Office ³	Number ⁴	Kind Code ⁵				
		FR	2 017 735		BYK-Gulden Lomberg Chemische Fabrik G.M.B.H.	5-22-1970	Eng. Language Translation Attached	

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Sheet 3 of 6

Application Number	09/924,319
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		5,814,332		Ghanta et al.	09/29/1998	
		5,409,711		Mapelli et al.	04/25/1995	
		5,489,436		Hoy et al.	02/06/1996	
		4,851,226		Julian et al.	07/25/1989	
		5,773,031		Shah et al.	06/30/1998	

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 4 of 6	Application Number	09/924,319
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	Group Art Unit	1616
	Examiner Name	Choi, Frank
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Von W. Roth and Unter Mitarbelt von K. Beschke, "Pharmakokinetik und Laxierende Wirkung von Bisacodyl nach Gabe verschiedener Zubereitungsformem, (Araneim-Forsch/Drug Res. 38(I), Nr. 4,1988) 570-574	
		Stephan R. Targan, "The Search for Pathogenic Antigens in Ulcerative Colitis" (Gastroenterology, Vol. 114. No. 5, 1998) 1099-1100.	
		Igor Laufer, "A Simple Method for Routine Double-Contrast Study of the Upper Gastrointestinal Tract" (Radiology, Vol. 117, No. 3,1975) 513-518.	
		Kazuo K. Kimura, Joseph F. Treon, and Frederic R. Benson, "Therapeutic Use of Methylopolysiloxane" (Current Therapeutic Research, Vol. 6, No. 3, 1964) 202-215.	
		D. M. Preston and J.E. Lennard-Jones, "Pelvic Motility and Response to Intraluminal Bisacodyl in Slow-Transit Constipation" (Digestive Diseases and Sciences, Vol. 30,No. 4, 1985), 289-294.	
		STN/CAS online, fie DRUGLAUNCH, Acc. No. 94:53778, Doc. No. 0107008 (Drug Launches (1993)). Abstract.	
		STN/CAS online, file EMBASE, Acc No. 91205342, Doc. No. 1991205342, (Wldgrube et al. Bildgebung (1991) 58/2 (63-66)), Abstract.	
		Brouwers, et al.; A Controlled Trial of Senna Preparations and Other Laxatives Used for Bowel Cleansing Prior to Radiological Examination; Pharmacology 20, Suppl. 1, 1980, pp. 58-64.	
		McNally et al.; The Effect of Simethicone on Colonic Visibility after Night-Prior Colonic Lavage, A double-Blind Randomized Study; J.Clin. Gastro,1989:11(6) p. 650-652.	
		Kark et al.; Improvement of Orthograde Golytely Colon Lavage by Additional Application of Simethicone; Z Gastroenterology 1995; 33: pp. 20-23	
		Lazzaroni et al.; Efficacy and Tolerability of Polyethylene Glycol-Electrolyte Lavage Solution With and Without Simethicone in the Preparation of Patients with Inflammatory Bowel Disease for Colonoscopy; Ailment Pharacol Ther. 1993: 3: pp. 655-659.	
		Shaver et al.; Improvement of Oral Colonic Lavage with Supplemental Simethicone; Digestive Diseases and Sciences, Vol. 33, No. 2, Feb. 1988, pp. 185-188.	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 5 of 6

Application Number	09/924,319
Filing Date	August 8, 2001
First Named Inventor	McNally
Group Art Unit	1616
Examiner Name	Choi, Frank
Attorney Docket Number	MCP0289

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Campieri et al.; Better quality of Therapy with 5-ASA Colonic Foam in Active Ulcerative Colitis: A Multicenter Comparative Trial with 5-ASA; Inst. Of Clin.ed & Gastro, Univ. of Bologna, Italy; Dig-Dis-Sci., Oct. 1993, 38 (10); p. 1843-50 (Abstract)	
		McNally et al; The Effectiveness of Simethicone in Improving Visibility During Colonoscopy: A double-Blind Randomized Study; Gastro. Endo., Vol. 34, No. 3, 1988, pp. 255-258.	
		Sudduth et al.; The Effectiveness of Simethicone in Improving Visibility During Colonoscopy when given with a Sodium Phosphate Solution; a Double-Blind Randomized Study; Gastro End., v. 52, No. 5, 1995 pp. 413-415.	
		Parikh & Khanduja; Use of Simethicone During Colonoscopy: Dis Colon Rectum, Sept. 1995, Letters to Editor, pp. 100-1008.	
		Stedman's Medical Dictionary, definition of "gastroparesis" and "diabetic," 27 th Edition, 2000, pp. 733 & 491	
		The Merck Index, Ed. by Susan Budavari, Pub'd. 1996, definition of "Bisacodyl," pp 1286	
		Lysy, Joseph et al., "Decreased Substance P Content in the Rectal Mucosa of Diabetics with Diarrhea and Constipation," Metabolism, Vol. 46, No. 7, pp. 730-734, 1997.	
		Lysy, J. et al., "Substance P Levels in the Rectal Mucosa of Diabetic Patients with Normal Bowel Function and Constipation," Scandinavian Journal of Gastroenterology, 28, (1), p. 49-52, 1993.	
		Lysy, J., "Rectal Mucosal content of substance P is increased in diabetic patients but lowered in those with diabetic constipation," Digestive Disease Week and the 92 nd Annual Meeting of the American Gastroenterological Association, New Orleans, LA, USA, cited in Gastroenterology, Vol. 100, No. 5, Part 2, pp. A466, 1991	
		Yerra, N., "Orally administered mustard (brassica) and turmeric (curcuma) reduce orocecal transit time," Am. J. Gastroenterol., 90, No. 9, 1668, 1995.	
		Holtman, G., "Simethicone and cisapride in functional dyspepsia: a double-blind randomized trial," Gastroenterology, Vol. 116, No. 4, pp. A196, Abstract No. G0819, 1999	

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 6 of 6	Application Number	09/924,319
	Filing Date	August 8, 2001
	First Named Inventor	McNally
	Group Art Unit	1616
	Examiner Name	Choi, Frank
	Attorney Docket Number	MCP0289

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Vazquez-Olivencia, W., "The effect of red and black pepper on orocecal transit time," Journal of the American College of Nutrition, Vol 11, No. 2, pp. 228-231, (1992)	
		Goodman and Gilman, "Agents Used to Treat Constipation: General Considerations," Section VI, Drugs Affecting Gastrointestinal Function, THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 2001, 10 th Edition, pp. 1042-1047	
		Goodman and Gilman, THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 1996, 9 th Edition, pp. 914-915, 917-925	
		Martindale The Extra Pharmacopoeia, "Gastro-Intestinal Agents," 29 th Edition, 1989, pp. 1073-1074	
		"Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph," Federal Register, Vol. 63, No. 118/ June 1998, pp. 33592-33595	

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Page 1 of 1

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Examiner Name	Choi, Frank
Attorney Docket Number	MCP 0289

U.S. PATENT DOCUMENTS

[illegible]

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		USSN 09/390,813 filed 09/0-7/1999 and published 28 March 2001 (Internal Ref. No. MCP 227)	
		USSN 09/538,008 filed 03/29/2000 (Internal Ref. No. MCP 255)	
		Partial European Search Report dated 6 November 2002 (MCP 227 EP) for EP 1 086 701 A3	

Examiner Signature		Date Considered	
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